
Anthrax Vaccination in the Millennium Cohort

Validation and Measures of Health

Besa Smith, MPH, Cynthia A. Leard, MPH, Tyler C. Smith, MS, Robert J. Reed, MS, Margaret A. K. Ryan, MD, MPH, for the Millennium Cohort Study Team

Background: In 1998, the United States Department of Defense initiated the Anthrax Vaccine Immunization Program. Concerns about vaccine-related adverse health effects followed, prompting several studies. Although some studies used self-reported vaccination data, the reliability of such data has not been established. The purpose of this study was to compare self-reported anthrax vaccination to electronic vaccine records among a large military cohort and to evaluate the relationship between vaccine history and health outcome data.

Methods: Between September 2005 and February 2006 self-reported anthrax vaccination was compared to electronic records for 67,018 participants enrolled in the Millennium Cohort Study between 2001 and 2003 using kappa statistics. Multivariable modeling investigated vaccination concordance as it pertains to subjective health (functional status) and objective health (hospitalization) metrics.

Results: Greater than substantial agreement ($\kappa=0.80$) was found between self-report and electronic recording of anthrax vaccination. Of all participants with electronic documentation of anthrax vaccination, 98% self-reported being vaccinated; and of all participants with no electronic record of vaccination, 90% self-reported not receiving a vaccination. There were no differences between vaccinated and unvaccinated participants in overall measures of health. Only the subset of participants who self-reported anthrax vaccination, but had no electronic confirmation, differed from others in the cohort, with consistently lower measures of health as indicated by Medical Outcomes Study 36-Item Short Form Health Survey for Veterans (SF-36V) scores.

Conclusions: These results indicate that military members accurately recall their anthrax vaccinations. Results also suggest that anthrax vaccination among Millennium Cohort participants is not associated with self-reported health problems or broad measures of health problems severe enough to require hospitalization. Service members who self-report vaccination with no electronic documentation of vaccination, however, report lower measures of physical and mental health and deserve further research.

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Introduction

Anthrax vaccine was first broadly administered to military personnel during the 1991 Gulf War, when as many as 150,000 United States service members received one to two doses.^{1,2} Beginning in 1998, the U.S. Department of Defense (DoD) initiated the Anthrax Vaccine Immunization Program, which began to vaccinate all 2.4 million U.S. service members,

starting with those assigned to high-threat areas.^{1,3} Because of a low supply of the anthrax vaccine and other complications, the DoD scaled down vaccination efforts in 2000, but still attempted to vaccinate service members deployed to specific high-risk areas.^{1,4} Numerous public anecdotal reports questioning the safety of the anthrax vaccine have prompted much research on the subject. Service members' immunizations, including the anthrax vaccination, were captured elec-

From the Department of Defense, Center for Deployment Health Research, Naval Health Research Center, San Diego, California

The Millennium Cohort Study Team is composed of Paul Amoruso, MD, MPH (Army Research Institute of Environmental Medicine, Natick MA); Edward J. Boyko, MD, MPH (Seattle Epidemiologic Research and Information Center, Veterans Affairs Puget Sound Health Care System, Seattle WA); Gary D. Gackstetter, PhD, DVM, MPH (Department of Preventive Medicine and Biometrics, Uniformed Services University of the Health Sciences, Bethesda MD, and Analytic Services, Inc., ANSER, Arlington VA); Tomoko I. Hooper,

MD, MPH (Department of Preventive Medicine and Biometrics, Uniformed Services University of the Health Sciences, Bethesda MD); Gregory C. Gray, MD, MPH (College of Public Health, University of Iowa, Iowa City IA); James R. Riddle, DVM, MPH (Air Force Research Laboratory, Wright-Patterson Air Force Base OH); and Timothy S. Wells, DVM, PhD (Air Force Research Laboratory, Wright-Patterson Air Force Base OH).

Address correspondence and reprint requests to: Besa Smith, MPH, DoD Center for Deployment Health Research, Naval Health Research Center, P.O. Box 85122, San Diego CA 92186-5122. E-mail: Besa@nhrc.navy.mil.

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tronically beginning only in 1998, forcing early studies to rely on paper records or self-report of anthrax vaccination history,⁵⁻⁹ underscoring the importance of investigating the veracity of anthrax vaccination data.

Although previous studies have used self-reported anthrax vaccination data, the accuracy of self-report for anthrax vaccination has not been well established.^{6,10-14} Most studies on adult vaccinations to date have shown that self-report is a moderately reliable method to determine an individual's vaccination status.^{10,15-18} Research examining the validity of adult influenza and pneumococcal vaccination data indicate self-report to be highly sensitive (70%–100%) and moderately specific (22%–89%).^{15,17,19,20} These studies also show that self-reported influenza vaccination is more sensitive (94%–100%) than other self-reported vaccinations such as the pneumococcal vaccination (70%–97%). This may be due in part to shorter recall time, because the influenza vaccine is administered annually while the pneumococcal vaccine is usually administered only once.^{15,19,20} Using limited anthrax vaccine data from the 1991 Gulf War, the sensitivity of self-reported anthrax vaccination among Gulf War veterans was 73.9%.¹⁰ However, among Gulf War veterans with a documented anthrax vaccination, self-reported morbidity, including functional impairment, hospitalization, and limitation of employment, was higher among those who self-reported receiving the anthrax vaccine compared with those who reported not receiving or not knowing if they received the vaccine. Additional research suggests that 1991 Gulf War service members who used a vaccination record to self-report data were more likely to report receiving an anthrax vaccine compared with those who did not use a record, indicating some may have forgotten that they received the vaccine.¹² These studies suggest that self-reported anthrax vaccination data may be subject to recall and reporting bias. The purpose of this study is to compare the concordance of self-reported anthrax vaccination from a large, population-based cohort study with electronic vaccination records. Further, baseline measures of health will be described within the cohort to evaluate the relationship between subjective and objective vaccine history and health outcome data.

Methods

Population and Data Sources

The Millennium Cohort Study was launched in 2001 to evaluate risk factors related to military service that may be associated with long-term adverse health outcomes.^{21,22} The 77,047 participants used for these analyses enrolled in the study between 2001 and 2003, and were demographically representative of the invited sample. Participants deployed to the first Gulf War between 1990 and 1991 were excluded from the study population ($n=9251$) because the electronic vaccination database was not launched until 1998, and during the

Gulf War it was common to receive anthrax vaccination. Of the remaining 67,796 participants, 67,018 (98.9%) indicated whether they had ever received an anthrax vaccination, and they form the basis of this study. These analyses were conducted between September 2005 and February 2006.

Demographic data were obtained from the Defense Manpower Data Center, and included gender, birth date, highest education level, marital status, race/ethnicity, pay grade, service component (active duty or Reserve/Guard), service branch (Army, Navy, Coast Guard, Air Force, and Marines), occupation, and previous deployment experience to Southwest Asia, Bosnia, or Kosovo. Electronic anthrax vaccination status was determined from records maintained by the Defense Eligibility and Enrollment Reporting System (DEERS) at the Defense Manpower Data Center, Monterey Bay CA. Hospitalization data were obtained from the computerized databases of standardized discharge diagnoses for hospitalizations within the Military Health System and for hospitalizations billed to the DoD by nonmilitary facilities. These databases contain hospitalization summaries including dates of admission and discharge, and up to eight individual discharge diagnoses for each encounter, which are uniformly coded across U.S. military services. These data were linked by unique identifier to Millennium Cohort Study participants.

The baseline Millennium Cohort questionnaire consists of 67 items, including questions regarding vaccination, functional status, mental health, and other morbidity. Two questions regarding anthrax vaccination were asked. The first, "Have you ever received the anthrax vaccine?" was followed by "If YES, how many shots of the anthrax vaccine have you received?" To compare differences in functional and mental status, the Medical Outcomes Study 36-Item Short Form Health Survey for Veterans (SF-36V) was used.²³⁻²⁶ The SF-36V uses standardized scoring algorithms to assess eight health constructs: physical functioning, role limitations caused by physical problems, bodily pain, general health, vitality, social functioning, role limitations caused by emotional problems, and mental health.

Statistical Analyses

Vaccination concordance status was separated into four categories: respondents who self-reported not being vaccinated with concurrence from the electronic records, respondents who self-reported being vaccinated but electronic records showed no vaccination, respondents who self-reported not being vaccinated but electronic records showed at least one anthrax vaccination, and respondents who self-reported receiving vaccination with concurrence from the electronic records.

Descriptive measures were calculated to evaluate self-reported vaccination status compared with electronic vaccination records. Percent self-reporting vaccination among all participants with electronic documentation of anthrax vaccination, and percent self-reporting no vaccination among all participants with no electronic record of vaccination are reported.

The kappa statistic was used to measure the degree of nonrandom agreement between self-reported anthrax vaccination and electronic anthrax vaccine records.²⁷ Defined-agreement levels included "greater than substantial agreement" as a kappa (κ) between 0.8 and 1.0, "substantial

agreement" ($\kappa=0.6-0.8$), "moderate agreement" ($\kappa=0.4-0.6$), "fair agreement" ($\kappa=0.2-0.4$), and "slight or poor agreement" ($\kappa=0.0-0.2$).²⁸ A weighted kappa statistic was used to investigate the concordance between the number of self-reported anthrax vaccinations and the number of vaccinations recorded in the electronic database, including only participants who were identified as vaccinated by both sources.

Multivariable logistic regression was performed to evaluate associations between hospitalization and vaccination concordance status. Participants were classified as hospitalized if they were hospitalized for any cause, except for child-bearing reasons, in the 12 months prior to completing the survey. Analysis of covariance was performed to evaluate the association between functional status (SF-36V) and vaccination concordance. Functional status scales were scored with increasing score reflecting better functional health.²³⁻²⁶ Imputed values were used for missing questions if the respondent answered at least half of the questions in a scale. Values were imputed based on the mean of the score for the complete portion of that scale. If more than one half of the questions in a scale were missing the participant was not included in the analysis for that scale. Both logistic regression and analysis of covariance modeling adjusted for all demographic and military-specific variables. All data analyses were completed using SAS software (version 9.1, SAS Institute, Inc., Cary NC, 2004).

Results

Of the 67,796 Millennium Cohort participants that were not deployed to the first Gulf War, 67,018 (98.9%) completed the anthrax vaccination survey question. Most self-reported they had never received an anthrax vaccination ($n=46,945$; 70.0%). This agreed with electronic vaccination records for 46,612 (69.6%) participants. Participants who reported receiving an anthrax vaccination ($n=20,073$; 30%) and also had an electronic record indicating vaccination included 15,041 (22.4%) participants. The remaining 5365 (8.0%) participants had discordant results. Most discordance was defined by self-reported receipt of vaccination, whereas electronic records indicated no vaccination ($n=5032$; 7.5%). Finally, 333 (0.5%) participants reported not receiving a vaccination despite the indication of one or more anthrax vaccinations in the electronic records.

The demographic characteristics of these four vaccination groups were compared (Table 1). A greater proportion of those who had an electronically confirmed self-reported vaccination (concordant vaccinated) were male; previously deployed to Southwest Asia, Bosnia, or Kosovo; active duty; Air Force or Marine service members; and worked as combat or electrical/mechanical repair specialists than those whose self-report of not receiving a vaccination was confirmed by absence of an electronic record of vaccination (concordant unvaccinated). When compared with concordant vaccinated participants, proportionately more participants who self-reported being vaccinated without electronic confirmation were

in transitional occupations (relative $\%=2.1$), in the Navy or Coast Guard (2.0), older (1.6), less educated (1.4), and Reserve/Guard members (1.4).

Of all participants with electronic documentation of anthrax vaccinations, 98% self-reported being vaccinated, and of all participants with no electronic record of vaccination, 90% self-reported not receiving a vaccination (Table 2). The kappa statistic indicated greater than substantial agreement ($\kappa=0.80$). Of those whose self-report and electronic record reflected anthrax vaccination (concordant vaccinated) there was moderate agreement (weighted $\kappa=0.53$) for the number of anthrax vaccinations received.

Among active-duty service members, hospitalization rates for any cause in the year prior to survey participation were not significantly different between the vaccination groups, after adjustment for gender, age, education, marital status, race/ethnicity, previous deployment experience, pay grade, service component, service branch, and occupation (Table 3).

Adjusted SF-36V mean scores ranged from 62 to 95 for all participants (Table 3). Means were adjusted for gender, age, education, marital status, race/ethnicity, previous deployment experience, pay grade, service component, service branch, and occupation. Although SF-36V adjusted mean scores were relatively high for all functional health components in each vaccination group, significantly lower scores for all eight components were found among participants whose electronic records reflected no vaccination but who self-reported receiving the anthrax vaccination when compared to groups with concordant status. Additionally, the adjusted mean score for role limitations because of physical problems was significantly higher among the concordant vaccinated group compared with the concordant unvaccinated group.

Discussion

Previous studies have used self-reported anthrax vaccination status to compare vaccinated and unvaccinated participants on subjective and objective health measures.^{6,10,12,13} However, the validity of self-reported anthrax vaccination has not yet been well established. Overall, self-report and electronic records of vaccination were very consistent, with 92% of participants having identical responses from the two sources. Agreement levels²⁸ suggest that the overall kappa demonstrates greater than substantial agreement between electronic and self-reported anthrax vaccination ($\kappa=0.80$). Participants with electronic documentation of anthrax vaccinations also reported vaccination 98% of the time, which is higher than in a similar study conducted by Mahan et al.,¹⁰ where sensitivity of self-reported anthrax vaccination among Gulf War veterans was found to be 74%. The lower agreement in vaccination status, however, found by Mahan et al.,¹⁰ may be

Table 1. Characteristics of Millennium Cohort Study participants by anthrax vaccination status

Characteristic	Study sample <i>n</i> =67,018 % ^b	Anthrax vaccination status ^a			
		Concordant ^c unvaccinated <i>n</i> =46,612 <i>n</i> (%)	Discordant ^c self-report vaccinated <i>n</i> =5032 <i>n</i> (%)	Discordant ^c electronic vaccinated <i>n</i> =333 <i>n</i> (%)	Concordant ^c vaccinated <i>n</i> =15,041 <i>n</i> (%)
Gender					
Male	71.5	31,517 (67.6)	4041 (80.3)	254 (76.3)	12,110 (80.5)
Female	28.5	15,095 (32.4)	991 (19.7)	79 (23.7)	2,931 (19.5)
Age (years)					
17–24	21.4	9,634 (20.7)	1230 (24.4)	107 (32.1)	3,364 (22.4)
25–34	35.7	15,586 (33.4)	1611 (32.0)	144 (43.2)	6,564 (43.6)
35–44	30.1	14,412 (30.9)	1622 (32.2)	71 (21.3)	4,073 (27.1)
>44	12.8	6,962 (14.9)	565 (11.2)	11 (3.3)	1,038 (6.9)
Unknown	0.0	18 (0.0)	4 (0.1)	0 (0.0)	2 (0.0)
Education					
High school or less	48.6	22,988 (49.3)	3015 (59.9)	201 (60.4)	6,390 (42.5)
Some college	25.7	10,848 (23.3)	1065 (21.2)	79 (23.7)	5,253 (34.9)
Bachelor's degree	16.8	8,260 (17.7)	630 (12.5)	37 (11.1)	2,344 (15.6)
Master's/PhD	8.8	4,511 (9.7)	322 (6.4)	16 (4.8)	1,054 (7.0)
Unknown	0.0	5 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marital status					
Not married	39.2	18,271 (39.2)	2091 (41.6)	164 (49.3)	5,710 (38.0)
Married	60.9	28,341 (60.8)	2941 (58.5)	169 (50.8)	9,331 (62.0)
Race/ethnicity					
White non-Hispanic	70.1	32,702 (70.2)	3573 (71.0)	191 (57.4)	10,477 (69.7)
Black non-Hispanic	13.2	6,167 (13.2)	615 (12.2)	76 (22.8)	1,972 (13.1)
Other	16.4	7,548 (16.2)	818 (16.3)	64 (19.2)	2,564 (17.1)
Unknown	0.4	195 (0.4)	26 (0.5)	2 (0.6)	28 (0.2)
Recent deployment experience					
Deployment experience	29.1	8,893 (19.1)	2140 (42.5)	129 (38.7)	8,336 (55.4)
No deployment	70.9	37,719 (80.9)	2892 (57.5)	204 (61.3)	6,705 (44.6)
Military pay grade					
Enlisted	77.3	35,344 (75.8)	4190 (83.3)	287 (86.2)	11,965 (79.6)
Officer	22.7	11,268 (24.2)	842 (16.7)	46 (13.8)	3,076 (20.5)
Service component					
Reserve/Guard	53.4	24,867 (53.4)	1420 (28.2)	80 (24.0)	3,058 (20.3)
Active duty	46.7	21,745 (46.7)	3612 (71.8)	253 (76.0)	11,983 (79.7)
Branch of service					
Army	46.7	25,573 (54.9)	1563 (31.1)	115 (34.5)	4,030 (26.8)
Air Force	29.9	12,118 (26.0)	1033 (20.5)	95 (28.5)	6,768 (45.0)
Navy/Coast Guard	18.6	7,359 (15.8)	2023 (40.2)	90 (27.0)	2,957 (19.7)
Marines	4.9	1,562 (3.4)	413 (8.2)	33 (9.9)	1,286 (8.6)
Occupational category					
Combat specialists	19.6	8,546 (18.3)	1034 (20.6)	78 (23.4)	3,473 (23.1)
Electronic repair	8.9	3,656 (7.8)	57 (11.4)	24 (7.2)	1,705 (11.3)
Communications/intel	7.1	3,267 (7.0)	380 (7.6)	18 (5.4)	1,100 (7.3)
Healthcare specialists	10.6	5,863 (12.6)	303 (6.0)	21 (6.3)	906 (6.0)
Other technical	2.6	1,163 (2.5)	137 (2.7)	8 (2.4)	440 (2.9)
Functional support	20.5	10,341 (22.2)	852 (16.9)	77 (23.1)	2,463 (16.4)
Electrical/mechanic	14.4	5,480 (11.8)	1061 (21.1)	60 (18.0)	3,074 (20.4)
Craft workers	3.1	1,379 (3.0)	157 (3.1)	6 (1.8)	541 (3.6)
Service support	8.3	4,088 (8.8)	363 (7.2)	29 (8.7)	1,104 (7.3)
Trainees, others	4.8	2,813 (6.0)	172 (3.4)	12 (3.6)	234 (1.6)
Unknown	0.0	16 (0.0)	2 (0.0)	0 (0.0)	1 (0.0)

^aAll unadjusted associations between anthrax vaccination status and individual characteristics were statistically significant ($p<0.01$).^bPercents may not sum to 100 due to rounding.^cConcordant unvaccinated: both self-report and electronic database reflect no vaccination; discordant self-report vaccinated: self-reported vaccination but electronic database reflects no vaccination; discordant electronic vaccinated: self-reported no vaccination but electronic database reflects vaccination; concordant vaccinated: both self-report and electronic database reflect vaccination.

Table 2. Agreement^a between self-reported anthrax vaccination and electronic records

Self-report	Electronic record	
	Vaccine	No vaccine
Vaccine	15,041	5,032
No vaccine	333	46,612

^aAgreement measures for self-report are as follows: kappa=0.80; 98% of participants with electronic documentation of anthrax vaccination self-reported being vaccinated, 90% of participants with no electronic record of vaccination self-reported not receiving a vaccination.

because of a longer period between vaccination and recall in addition to differences in sample size and population.

Individuals whose electronic and self-reported anthrax vaccination status did not agree were more likely to be in transitional occupations, Navy/Coast Guard service members, older, less educated, and Reserve/Guard members when compared with participants whose electronic and self-reported vaccination status were in agreement. Previous studies have found lower education to be associated with lower rates of response,²⁹ higher rates of refusal,^{30,31} and lower rates of reliability in self-reported data,^{32,33} similar to the current study. Service-specific differences and differences found between Reserve/Guard and active-duty subgroups may be because of variations in procedures for reporting of vaccinations.

For all eight functional status components, participants whose self-reported vaccination was not confirmed by electronic record had lower adjusted mean scores, indicating worse health. These participants also had lower unadjusted means compared with national norms for ages 18–64 years for four of the eight scales.³⁴ The other three vaccination status groups had higher unadjusted means compared with the national norms for all components, except the concordant unvaccinated group, which had a lower bodily pain score. Although there has been little research to date linking anthrax vaccination concordance to functional health, at least one other previous study has indicated that individuals who otherwise fit our definition of “vaccination concordant” self-report significantly higher levels of functional impairment, healthcare utilization, and selected medical conditions.¹⁰ In contrast, those in our study whose self-report of vaccination was confirmed in the electronic database did not have significantly lower functional status scores, compared with those who self-reported and were confirmed unvaccinated. These results may indicate there are a small percentage of participants with lower functional status who reported being vaccinated that either did not actually receive an anthrax vaccine or received one that failed to show up in the electronic database. Although the likelihood exists that not all anthrax vaccinations are being documented in the military electronic data, these results may also suggest a small amount of report-

Table 3. Adjusted odds of hospitalization and adjusted means of SF-36V health scores among Millennium Cohort participants^a by anthrax vaccination status

Health outcome	Anthrax vaccination status			
	Concordant ^b unvaccinated	Discordant ^b self-report vaccinated	Discordant ^b electronic vaccinated	Concordant ^b vaccinated
	OR (95% CI) ^c	OR (95% CI)	OR (95% CI)	OR (95% CI)
Any cause hospitalization ^d	1.00	1.08 (0.88–1.32)	1.61 (0.89–2.90)	0.95 (0.82–1.09)
SF-36V ^e	Mean	Mean	Mean	Mean
Physical functioning	92.1 ¹	89.6 ²	92.1 ^{1,2}	92.5 ¹
Role physical	93.9 ¹	91.1 ²	94.2 ^{1,3}	94.6 ³
Bodily pain	78.5 ¹	74.5 ²	79.6 ¹	78.8 ¹
General health	80.3 ¹	76.9 ²	81.5 ¹	80.6 ¹
Social functioning	88.8 ¹	85.2 ²	89.6 ¹	89.0 ¹
Role emotional	94.3 ¹	92.3 ²	93.7 ^{1,2}	94.7 ¹
Mental health	80.2 ¹	78.0 ²	80.7 ¹	80.3 ¹
Vitality	64.4 ¹	62.1 ²	66.6 ¹	64.5 ¹

^aParticipants with missing covariate data ($n=294$) or whose SF-36V component could not be scored due to insufficient questionnaire responses were removed from analyses (n varies by component, maximum removed 347).

^bConcordant unvaccinated: both self-report and electronic database reflect no vaccination (reference group); discordant self-report vaccinated: self-reported vaccination but electronic database reflects no vaccination; discordant electronic vaccinated: self-reported no vaccination but electronic database reflects vaccination; concordant vaccinated: both self-report and electronic database reflect vaccination.

^cOdds ratio (OR), 95% confidence interval (CI), and mean are adjusted for gender, age, education, marital status, race/ethnicity, deployment status, pay grade, service component (SF-36V only), service branch, and occupation.

^dHospitalization analysis includes active-duty service members only, and reflects odds of any-cause admission in year prior to survey response.

^eSF-36V, Medical Outcomes Study 36-Item Short Form Health Survey for Veterans.

^{1,2,3}Different numbers indicate vaccination status scores that are significantly different from each other ($p<0.05$) using Scheffe's adjustment for multiple comparisons.

ing and/or recall bias with this question in the Millennium Cohort questionnaire.

There are notable limitations to these analyses that should be mentioned. The study population consists of a sample of responders to the Millennium Cohort questionnaire, and may not be representative of the U.S. military population in general. Those who might be severely ill may not choose to respond or have the capacity to do so. The kappa statistic is dependent on the true prevalence of the variable being examined, with the kappa statistic tending toward zero as the true prevalence approaches 0 or 1.³⁵ However, because a considerable percentage of U.S. military service members were receiving anthrax vaccines from the late 1990s to the early 2000s, this dependence on prevalence should not substantially affect these findings. It should be noted that the electronic vaccination database includes anthrax vaccinations only from 1998 onward. However, those that were most likely to have received the anthrax vaccine before 1998, namely those deployed to the first Gulf War, were excluded from this study. Additionally, quantifying the level of incomplete documentation in the DoD electronic vaccination database for anthrax vaccination remains a challenge. Medical records, if available, may have provided additional vaccination history. Recent research, however, shows a strong level of agreement between electronically maintained anthrax vaccination records and anthrax vaccination data abstracted from medical charts.³⁶

Despite these limitations, this study has several strengths. The large sample size allowed for the robust comparison of self-report and objective measures of anthrax vaccination. Furthermore, this study was able to link both objective and subjective measures of morbidity to self-reported and electronically recorded vaccination status. This has not been previously done in a single population.

In summary, military service members represent a unique population that relies on advanced protection during deployment and combat situations. Vaccines against biologic agents are an important component of protection. It is of further importance to the healthcare community to be able to document the use of vaccines, such as anthrax, and investigate potential associations between vaccination and morbidity.^{7,37–39} This analysis found that most people accurately recall their vaccination history. In addition, no differences in health, as defined objectively by morbidity severe enough to require hospitalization, were found by vaccine history. However, service members who self-reported receiving the anthrax vaccine with no objective evidence of vaccination reported more health difficulties. Further investigation into this subset will add important insight into those who may indiscriminately report more exposures as well as more health challenges.

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This research has been conducted in compliance with all applicable federal regulations governing the protection of human subjects in research (Protocol NHRC.2000.007).

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